K001215

JUN 2 2 2000

510 (K) summary

The **dBest** One Step hCG Inhibition Test is a chromatographic immunoassay which use specific antibodies to selectively identify hCG in urine with a sensitivity of 2 IU/ml hCG (2^{nd} international Standard).

The dBest AmeriTek test kit is 88% in agreement with a commercially available test kit for 90 urine samples and 100% in agreement with standard positive control. The test kit sensitivity is 2 IU/ml of hcg.

None of the potentially interfering substances interfered with hCG in urine when using the dBest hCG test procedure.

The ability of the **dBest** hCG Inhibition Test to specifically detect hCG was challenged through cross-reaction studies on urine samples containing known quantities of structurally and physiologically related hormones. Five urine samples spiked with 500mIU/ml LH (human Luteinizing Hormone), 1000 mIU/ml FSH (Follicle Stimulating Hormone),1000 μIU/ml TSH (Thyroid Stimulating Hormone) shows negative results only

The precision study shows that 96% samples containing hCG concentrations at the cutoff showed positive results and 100% samples showed negative results at concentration 25% below the cutoff and 100 % samples showed positive results at 25% above cutoff concentration.

The summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I certify that K.C.Yee will make available all information included in the premarket notification of safety and effectiveness that supports a finding of substantial equivalence within 30 days of request by any person. The information I agree to make available dose not include confidential patient identifiers of confidential or trade secret manufacturing process information.

K.C. Yee,MD., Ph.D.
President
April 10, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 22 2000

K. C. Yee, M.D., Ph.D.
President
Ameritek, Inc.
7030 35th Avenue NE
Seattle, Washington 98115

Re: K001215
Trade Name: dBest hCG 2 IU/ml Test Kits
Regulatory Class: II
Product Code: JHI
Dated: May 18, 2000
Received: May 22, 2000

Dear Dr. Yee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (K) Number (if known): K001215

Device Name: dBest hCG 2 IU/ml Test Kits

Indications For Use:

The dBest hCG Test Kit is a simple one step immunochromatographic assay for rapid, qualitative detection of chorionic gonadotropin (hCG) in urine with cutoff of 2 IU/ml. The dBest hCG Test Kits are for professional and laboratory use only.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001215

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PATE IF NEEDEN)

Prescription Use ✓ OR Over-The -Counter Use _____